

invention would not result in significantly changed structural properties. With respect to Page 14, Lines 22-24, Applicant believes that the deleted portions of these sentences are inconsistent with the remainder of the specification. See, e.g., Appl'n, Page 14, Lines 5-7. Applicant is including a marked-up copy of the amendments to the claims, the specification, and drawings with this responsive amendment. No new matter is added by the foregoing amendments, and these amendments are fully supported by the specification. See, e.g., Appl'n, Page 14, Lines 1-15. Applicant respectfully requests that the Examiner reconsider the above-captioned patent application in view of the foregoing amendments and the following remarks.

REMARKS

1. Objections and Rejections

Applicant acknowledges with appreciation that the Examiner indicates that claims 7-11, 14, 17, 20, 23, 26, 33-37, 42, and 43 would be allowable if rewritten in independent form. Nevertheless, claim 32 stands rejected under 35 U.S.C. § 112, ¶ 1, as allegedly containing subject matter that was not described sufficiently to enable one skilled in the art to make or use the invention. Further, claims 12, 30, and 33 stand objected as allegedly containing informalities, and claims 15-17, 21, 31, and 40 stand rejected under 35 U.S.C. § 112, ¶ 2, as allegedly being indefinite. Moreover, claims 1, 2, 12, 13, 15, 16, 18, 19, 21, and 22 stand rejected under 35 U.S.C. § 102(b), as allegedly being anticipated by U.S. Patent No. 3,818,511 to Goldberg et al. ("Goldberg"); and claims 1-6, 24, 25, 27-31, 38, 39, and 40 stand rejected under 35 U.S.C. § 102(e), as allegedly being anticipated by U.S. Patent No. 5,989,287 to Yang et al. ("Yang"). In addition, claims 41 and 44-53 stand rejected under 35 U.S.C. § 103(a), as allegedly rendered obvious by Yang in view of U.S. Patent No. 4,173,689 to Lyman et al. ("Lyman"); and claims 54-57 stand rejected under 35 U.S.C. § 103(a), as allegedly rendered obvious by Yang in view of Lyman and further in view of U.S. Patent No. 5,116,360 to Pinchuk et al. ("Pinchuk"). Applicant respectfully traverses.

1. Informalities and Indefiniteness Rejections

The Office Action objects to claims 12, 30, and 33 as allegedly containing informalities and rejects claims 15-17, 21, 31, and 40 as allegedly indefinite. The Office Action identifies the alleged informalities in each of claims 12, 30, and 33, and Applicant has amended

each of claims 12, 30, and 33 to eliminate the alleged informalities. The Office Action also indicates that elements of claims 15, 21, and 40 allegedly lack antecedent basis. Applicant has amended claims 15, 21, and 40 to overcome these alleged deficiencies. Moreover, by the foregoing amendments, Applicant respectfully traverses the Office Action's objections to the alleged informalities and the indefiniteness rejections to claims 12, 15-17, 21, 30, 33, and 40. Therefore, Applicant respectfully requests that the Examiner withdraw his objections and rejections to these claims.¹

2. Enablement Rejection

As noted above, claim 32 stands rejected as allegedly containing subject matter that was not described in the specification. In particular, the Office Action maintains that the term "end-capped with dibutylamine" was not described in the specification. However, the Office Action does not comment on a similar limitation in claim 6. Applicant respectfully disagrees.

In the application, Applicant states that the polyether urethane-urea is end-capped with dibutylamine. Appl'n, Page 14, Lines 1-15. The process of "end-capping" is known in the art as a type of chain-termination, which is described in U.S. Patent Nos. 5,936,047 and 4,071,505 (copies enclosed) and H. Keul *et al.*, Synthesis of Telechelics and Block Copolymers Via Living Radical Polymerization, <http://material.imc.cas.cz/sympo/39micros/speclect.htm> (copy enclosed). In the Brief Description of Related Art in U.S. Patent No. 5,936,047, the patentee states that

Generally, the degree of polymerization is controlled by the proportion of at least one reactant in the polymerization. Often the controlling reactant is a compound which, when incorporated into the polymerization reaction, terminates the forming polymer chain. Such compounds are sometimes referred to as "endcappers" or "chain-stoppers."

¹ Applicant is amending claims 7 and 33 to remove the phrase "comprising polymeric solids," which is believed to be redundant in the contexts of these claims.

U.S. Patent No. 5,936,047, Column 1, Lines 15-21. Applicant maintains that the process is known to persons skilled in the art and that no further description is required. MPEP 2164.04. Therefore, Applicant respectfully requests that the Examiner withdraw the enablement rejection.

3. Anticipation Rejections

a. Goldberg

As noted above, the Office Action rejects claims 1, 2, 12, 13, 15, 16, 18, 19, 21, and 22, as allegedly anticipated by Goldberg. "A claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference." MPEP 2131 (citation omitted). The Office Action alleges that Goldberg describes each and every element as set forth in claims 1, 2, 12, 13, 15, 16, 18, 19, 21, and 22. Applicant respectfully disagrees.

Goldberg at least does not disclose a bypass graft with a flared portion that is formed integrally on an end of a tubular portion, as recited in claim 1. Claim 1 recites a bypass graft with "a tubular portion . . . a flared portion having an adjoining end, wherein said adjoining end of said flared portion is integrally formed on . . . said second end of said tubular portion." See Appl'n, Page 6, Lines 3-9; Page 7, Lines 18-29; Page 9, Lines 12-27; **Figs. 1-4, 6**. However, Goldberg discloses a bypass graft in which a flared portion, e.g., funnel assembly 1, is not formed integrally on a tubular portion, e.g., cannula 2. Funnel assembly 1 includes a cloth skirt 3 embedded in walls of funnel mouth 4 at joint 5 and a shank 6 connecting funnel mouth 4 with a connector portion 7. Connector portion 7 seats funnel assembly 1 on an end 8 of a cannula 2. Goldberg, **Figs. 1, 3, and 4**; Column 3, Line 51 to Column 4, Line 2. Thus, funnel assembly 1 is not formed integrally on tubular portion 2, as recited in Applicant's claim 1. Instead, the bypass graft of Goldberg requires assembly and use of an adhesive to connect the funnel assembly 1 and tubular portion 2. Goldberg, Column 3, Line 51 to Column 4, Line 2.

Claims 2, 12, 13, 15, 16, 18, 19, 21, and 22 depend from claim 1 and include all of the limitations of claim 1. Consequently, Applicant also respectfully requests that the Examiner withdraw the anticipation rejection of claims 2, 12, 13, 15, 16, 18, 19, 21, and 22, at least for the reasons discussed above.

b. Yang

As noted above, the Office Action rejects claims 1-6, 24, 25, 27-31, 38, 39, and 40, as allegedly anticipated by Yang. Again, Applicant respectfully disagrees.

Yang at least does not disclose a bypass graft with a flared portion formed integrally on an end of a tubular portion, as recited in Applicant's claim 1. Instead, Yang discloses a bypass graft with a flared portion, e.g., support rings 26a, 26b, connected to each respective end of a tubular portion, e.g., cannula 22. Yang, Column 3, Line 33 to Column 4, Line 10; Column 5, Line 5 to Column 6, Line 50, **Figs. 1-9**. Moreover, in most embodiments, Yang discloses an autogenous cannula, e.g., a saphenous vein, and prosthetic support rings, making an integral formation between these elements problematic. Yang, Column 5, Lines 5-33; **Figs. 1-10**. An embodiment with a prosthetic cannula comprises support rings made of an elastic material which material matches the mechanical properties of the tissue to which they are attached, while the prosthetic cannula 132 is made of a non-expandable material. Yang, Column 5, Line 45 to Column 6, Line 6; Column 10, Lines 23-45.

Claims 2-6, 24, 25, 27-31, 38, 39, and 40 depend from claim 1 and include all of the limitations of claim 1. Consequently, Applicant further requests that the Examiner withdraw the anticipation rejection of claims 2-6, 24, 25, 27-31, 38, 39, and 40, at least for the reasons discussed above.

4. Obviousness Rejections

a. Yang and Lyman

As noted above, the Office Action rejects claims 41 and 44-53 under 35 U.S.C. § 103(a), as allegedly rendered obvious by Yang in view of Lyman. In order for the Office Action to establish a prima facie case of obviousness, at least three criteria must be met. First, there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to those of ordinary skill in the art, to modify the primary reference as proposed by the Office Action. Second, there must be a reasonable expectation of success. Third, the prior art references must disclose or suggest all of the claim limitations.

MPEP 2143. For the reasons set forth below, Applicant maintains that the Office Action fails to establish a prima facie case of obviousness.

Yang at least does not disclose the steps of “providing a mandrel having a tubular portion and a flared end bulb with a flared end central axis; forming at least one layer of polyurethane over said mandrel; drying said at least one layer of polyurethane . . . ; forming a skirt edge around said flared end bulb of said mandrel to form an opening at a predetermined angle . . . ; forming a second edge around said tubular portion of the mandrel; and removing said graft from said mandrel,” as recited in Applicant’s claim 41. The Office Action concedes that Yang does not disclose these steps of manufacturing a bypass graft, as recited in claim 41. Office Action, Page 5, Lines 1-6. However, the Office Action alleges that Lyman discloses a method of manufacturing a bypass graft. Applicant respectfully disagrees.

Lyman at least does not disclose the steps of providing a mandrel with a tubular portion and a flared end bulb, forming a skirt edge around the flared end bulb of the mandrel to form an opening at a predetermined angle, or forming a second edge around said tubular portion of the mandrel, as recited in Applicant’s claim 41. Lyman, Column 6, Line 67 to Column 7, Line 2. The disclosure in Lyman of a method for the “fabrication of numerous shapes and forms by varying the surface configuration of the forming device utilized in the precipitation process” does not disclose the method steps of claim 41. Lyman, Column 6, Line 67 to Column 7, Line 2.

The combination of Lyman and Yang does not disclose the method of Applicant’s claim 41. Yang discloses a bypass graft in which support rings are connected to ends of an autogenous or synthetic cannula. Because the mechanical properties of the support rings differ from those of the autogenous or prosthetic cannula to which the support rings are attached, the bypass graft of Yang may not be produced by the method of claim 41 or the method of Lyman. Yang, Column 3, Lines 60-67; Column 5, Line 64 to Column 6, Line 6; Column 10, Lines 23-28. In fact, the Office Action has not identified any motivation for combining Lyman and Yang to disclose the method of Applicant’s claim 41 other than Applicant’s disclosure. Thus, in addition to the distinctions discussed above, the Office Action’s combination of Lyman and Yang is based on improper hindsight, using the disclosed invention as the source of any motivation for combining Lyman and Yang, allegedly to disclose the invention.

Claims 42-53 depend from claim 41 and include all of the limitations of Applicant's claim 41. If an independent claim is nonobvious under 35 U.S.C. § 103, then any claim depending therefrom is nonobvious. MPEP 2143.03. Consequently, Applicant respectfully requests that the Office Action withdraw the obviousness rejection of claims 42-53, as least for the reasons stated above.

b. Yang, Lyman, and Pinchuk

As noted above, the Office Action rejects claims 54-57, as allegedly rendered obvious by Yang, in view of Lyman and further in view of Pinchuk. Because claims 54-57 depend from claim 41 and include all of the limitations of Applicant's claim 41, Applicant respectfully requests that the Examiner withdraw the obviousness rejection of claims 54-57, at least for the reasons discussed in Applicant's analysis of the Office Action's rejection of independent claim 41. See MPEP 2143.03.

CONCLUSION

Applicant respectfully submits that this application, as amended, is in condition for allowance, and such disposition is earnestly solicited. If the Examiner believes that an interview with Applicant's representatives, either in person or by telephone, would expedite prosecution of this application, we would welcome such an opportunity. No fees are due as a result of this responsive amendment. Nevertheless, in the event of any variance between the fees determined by Applicant and those determined by the U.S. Patent and Trademark Office, please

charge any such variance to the undersigned's Deposit Account No. 02-0375.

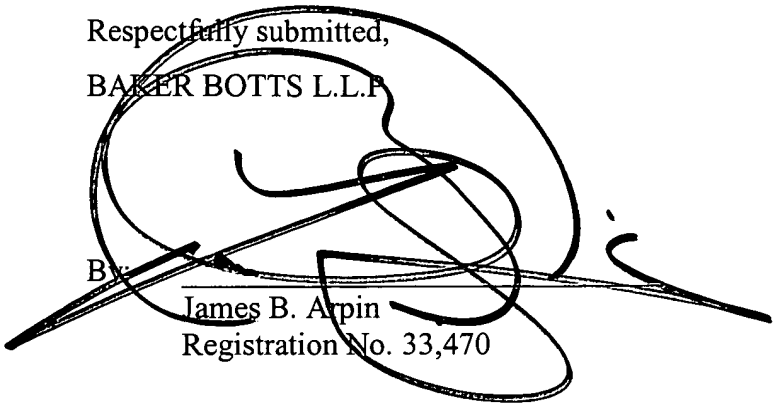
Respectfully submitted,
BAKER BOTTS L.L.P.

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Baker Botts LLP
The Warner; Suite 1300
1299 Pennsylvania Avenue, N.W.
Washington, D.C. 20004-2400
(202) 639-7700 (telephone)
(202) 639-7890 (facsimile)

JBA/dh

Enclosures

By: 
James B. Arpin
Registration No. 33,470

MARKED-UP COPY OF AMENDMENTS

IN THE SPECIFICATION:

Please replace the paragraph at Page 8, Lines 12-18, with the following replacement paragraph:

A third zone 66 also may contain [wound reinforcement wires or fibers] reinforcing members 68 to prevent the collapse and kinking of the CABG. As with second zone 64, third zone 66 may be formed from segmented polyether-polyurethane. During the formation of this zone, however, salt particulates, such as sodium chloride particulates with an average diameter of less than about 38 microns and a range of diameters between about 15 and about 115 microns, may be used to form pores of corresponding sizes. In an embodiment, third zone 66 may have a radial thickness of about 400 to about 3200 microns.

Please replace the paragraph at Page 14, Lines 16-28, with the following replacement paragraph:

In such admixtures , the base polymer is the polymer, whose surface characteristics are modified by the addition of the additive. As noted above, preferably, the surface characteristics are modified to achieve a low surface free energy or a high contact angle of adhesion, or both. [The additive also may be selected to improve the structural properties, e.g., flexibility, softness, and strength, of the base polymer.] Generally, the additive has a significantly lower γ_c value than that of the base polymer. The admixture's γ_c value may be reduced by dispersing the additive throughout the base polymer. Preferably, the additive is [a thermoplastic, fusible material that is] soluble in a solvent and relatively uncrosslinked. Such an additive may be [solidified and] formed into the blood contacting layer (or zone), e.g., first zone 62 in **Fig. 6**. The additive's surface free energy may be in a range of about 10 to about 35×10^{-5} N/cm (about 10 to about 35 dyne/cm). More preferably, its surface free energy is less than about 30×10^{-5} N/cm (about 30 dyne/cm), and an optimum surface free energy may be in a range of about 20 to about 25×10^{-5} N/cm (about 20 to about 25 dyne/cm).

IN THE DRAWINGS:

Please replace **Fig. 6**, as originally filed, with replacement **Fig. 6**, which corrects the position of reinforcing members 68 in the lower portion of the figure.

IN THE CLAIMS:

Please amend claims 7, 12, 15, 21, 30, 31, 33, and 40, as follows:

7. (amended) The graft of claim 1, wherein said graft comprises:
an inner first micro-porous layer of polyether urethane-urea [comprising polymeric solids] comprising about 1% to about 5% by weight of an additive formed by condensing MDI [NMI], polydimethylsiloxane, and 1,4-butanediol;
a second nonporous layer of polyether urethane-urea [comprising polymeric solids] comprising about [4.5%] 1% to about 5% by weight of said additive; and
a third porous layer of a polyether urethane-urea [comprising polymeric solids] comprising about [3.5%] 1% to about 5% of said additive.
12. (amended) The graft of claim 1, wherein said flared end has a flared end central axis, which is at an oblique angle to said central axis of said tubular portion.
15. (amended) The graft of claim 1, wherein said circumferential skirt [member] is oriented for attaching at an acute angle to said blood vessel.
21. (amended) The graft of claim 1 wherein said circumferential skirt [member] is elongated.
30. (amended) The graft of claim 29, wherein said polyurethanes comprise[s] a polyether urethane-urea.
31. (amended) The graft of claim 30 [29], wherein said polyether urethane-urea further comprising an additive in the amounts in a range of about 1% to about 5% by weight, said additive formed by condensing a combination of MDI, polydimethylsiloxane, and 1,4-butanediol.
33. (amended) The graft of claim 27, wherein said graft comprises:
an inner first micro-porous layer of polyether urethane-urea [comprising polymeric solids] comprising about 1% to about 5% by weight of an additive formed by condensing MDI [NMI], polydimethylsiloxane, and 1,4-butanediol;
a second nonporous layer of polyether urethane-urea [comprising polymeric solids] comprising about [4.5%] 1% to about 5% by weight of said additive; and
a third porous layer of a polyether urethane-urea [comprising polymeric solids] comprising about [3.5%] 1% to about 5% of said additive.
40. (amended) The graft of claim[s] 27, wherein said circumferential skirt [member] is elongated.

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SYNTHESIS OF TELECHELICS AND BLOCK COPOLYMERS VIA LIVING RADICAL POLYMERIZATION

H. KEUL, A. NEUMANN, B. REINING, H. HÖCKER

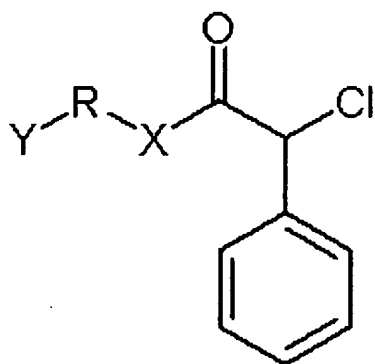
Lehrstuhl für Textilchemie und Makromolekulare Chemie der Rheinisch-Westfälischen Technischen Hochschule Aachen, Worringerweg 1, 52056 Aachen, Germany

The atom transfer radical polymerization (ATRP) of styrene (St) and methyl methacrylate (MMA) with a macroinitiator **1** ($\text{RX} = (\text{CH}_2\text{CH}_2\text{O})_n$; $\text{Y} = \text{OCH}_3$) based on poly(ethylene oxide) leads to block copolymers with a controlled molecular weight and a narrow molecular weight distribution.

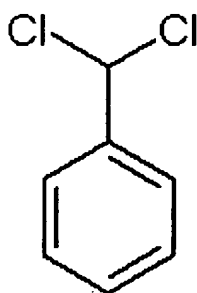
Polymerization of St and MMA with a low molecular weight initiator **1** ($\text{Y} = \text{OH}$, $\text{R} = (\text{CH}_2)_n$, and $\text{X} = \text{O}$ or NH) leads to a well defined heterotelechelic product with the endgroups defined by the initiator used.

Polymerization of both St and MMA with benzylidene chloride (**2**) as initiator leads to a chlorotelechelic product; however, in the polymerization of St a monodirectional chain growth and in the polymerization of MMA a bidirectional chain growth is observed.

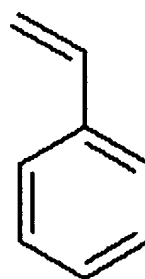
The atom transfer radical polymerization of both St and MMA can be terminated by endcapping the chains with an ω -functional α -olefin as for example the endcapping agent AA ($\text{R}' = \text{H}$ or $\text{CO-NH-C}_6\text{H}_4\text{CH}_3$). Thus, additional functional groups can be introduced as the chain end(s) by a new type of a chain analogous reaction, the atom transfer radical addition.



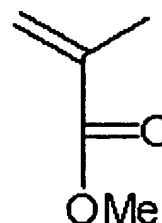
1



2



St



MMA

COPY